DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

SUBJECT: Management of the office of human research protection program and IRB	Policy #: CRP-1042
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DEPARTMENT: DHR Health Institute for Research & Development	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21

Purpose: The HRPP and IRB Committee are managed as determined by the Institutional Official. Management on a day-to-day basis is carried out under the direction of the HRPP Leadership Team which consists of the IRB Chair, Co-Chair and Coordinator operating under broad delegated authority from the Institutional Official.

Applies To:
This policy applies to the following potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

Institutional Official:
The DHR Health Institute for Research and Development Board of Directors, has delegated authority and responsibility for the Human Research Protection Program (HRPP) to the President of the DHR Health Institute for Research and Development (i.e., the Institutional Official).

The HRPP and IRB Committee are managed as determined by the Institutional Official. Management on a day-to-day basis is carried out under the direction of the HRPP Leadership Team which consists of the IRB Chair, Co-Chair and Coordinator operating under broad delegated authority from the Institutional Official.
The Institutional Official ensures that adequate facilities, equipment, and resources are available to support the IRB-related activities of the HRPP Leadership Team and IRB Office staff. The Institutional Official is also responsible for approving organizational relationships with other institutions or sites wherein the human subject research activities of University faculty, students or staff or UPMC staff may or will be conducted.

Legal Counsel
The Office of Human Research Protection Program consults regularly with the DHR Health Legal Counsel with respect to legal issues that arise during the review of human subject research. This includes a review of instances where the Office of Human Research Protection Program has identified a potential conflict between federal and state and local laws, and determines whether federal has pre-empted state and local laws, or whether the conflict may be reconciled in a manner that avoids a direct conflict between federal and state laws. The Office of Human Research Protection Program along with the help of legal counsel shall ensure that all research activities are compliant with applicable federal and state laws including Mandatory Reporting.

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Mandatory Reports includes the following circumstances:

- Child Abuse or Neglect- Professionals are required to report not later than the 48th hour after the professional has cause to believe the child has been or may be abused or is the victim of the offense of indecency with a child and the professional has cause to believe the child has been abused.
- Abuse, Neglect or Exploitation of Elderly or Disabled Persons- A person having cause to believe that an elderly or disabled person is in the state of abuse, neglect, or exploitation shall report immediately to the Department of Protective and Regulatory Services.
- Notifiable Condition- A physician, dentist, chiropractor, advanced practice nurse, physician assistant, or person permitted by law to attend to a pregnant women during gestation or at the delivery of an infant shall report, as required by these sections, each patient he or she shall examine and who has or is suspected of having any notifiable condition, and shall report any outbreak, exotic disease, or unusual group expression of illness of any kind whether or not the disease is known to be communicable or reportable.
- Cancer- All laboratories, hospitals, facilities and practitioners are required to report to the Department of Health within 6 months of diagnosis any cancer in an individual if making the initial diagnosis. The report includes the diagnosis, occupation, family history and personal habits of the person diagnosed with cancer.

Appointment of IRB Chair, Vice Chair

The IRB Chair and IRB Co-Chair will be appointed by the Institutional Official.

1. In appointing the IRB Chair, IRB Vice Chair primary consideration will be given to current or past members of the IRB.
2. The IRB Chair should be a highly respected individual fully capable of managing the IRB committee and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of this individual.
3. Vice Chairs are appointed based on previous experience as an IRB member and/or past experience in the conduct of human subject research.
4. The terms of appointment of the IRB Chair and Vice Chair is a maximum of three years.

Only the Institutional Official has the authority to terminate the appointment of the IRB Chair and ViceChair. Termination of appointment (i.e., by the Institutional Official) or resignation of appointment by the IRB Chair or Co-chair shall be subject to a minimum of 3 months advanced notice unless extenuating circumstances exist.

Responsibilities of the IRB Chair

The IRB Chair will hold leadership responsibility for IRB review and approval of human subject research in accordance with current guidelines, institutional policies, and federal and state regulations governing human subject protections. In addition, the IRB Chair will:

- oversee the recruitment, orientation, continuing education and retention of IRB members;

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- oversee the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the IRB. The IRB Chair or his/her designee is responsible for reviewing the IRB's policies and procedures for currency, accuracy and consistency on an ongoing basis but not less than every three years. Ad hoc committees may be formed to review guidance issued by regulatory agencies to determine whether updates to the policies and procedures are required;
- have authority to request audits of human subject research activities;
- have the authority to suspend some or all research activities if exceptional human subject safety issues are identified. (Note that this authority is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting). When this authority is exercised, it will be reported at the next convened IRB meeting;
- represent the IRB in interactions related to issues surrounding the ethical and regulation-compliant conduct of human subject research;
- approve written correspondence to state and federal regulatory agencies having jurisdiction over human subject research prior to final approval and signature of the Institutional Official;
- represent the IRB at national and local meetings related to institutional review board activities and human subject protections.

All research investigators involved in the conduct of human subject research that falls under the authority of the IRB take direction from the IRB Chair.

Responsibilities of the IRB Vice Chair
The primary responsibilities of the IRB Vice Chair are to the assist the IRB Chair in the:

- leadership responsibility for IRB review and approval of human subject research studies in accordance with current guidelines, institutional polices, and federal and state regulations governing human subject protections;
- recruitment, orientation, continuing education and retention of IRB members;
- development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the IRB.

In addition, the vice chair is to serve as a voting member of the IRB. They are also expected to represent the DHR Health Institute for Research and Development at national and local meetings related to IRB activities and human subject protections.

Responsibilities of the IRB Coordinator
The IRB Coordinator provides day to day oversight of the operations of the IRB. In addition, the IRB Coordinator is also responsible for assisting the IRB Chair and Vice Chair in:

- Assist the Chair and Vice Chair in the review and approval of all submitted research studies
- the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the IRB;

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- interactions related to issues surrounding the ethical and regulatory-compliant conduct of human subject research;
- the drafting of written correspondence to state and federal regulatory agencies having jurisdiction over human subject research activities.
- Organize the monthly institutional review board committee meetings
- Development and approval of the IRB meeting minutes